Practical Radiation Oncology (2014) 4, 215-216

practical radiation oncology

pro

www.practicalradonc.org

Commentary

The safety hazard

Louis Potters MD, FACR, FASTRO*, Ajay Kapur PhD

Department of Radiation Medicine, North Shore-LIJ Health System, New Hyde Park, New York

Received 1 November 2013; accepted 4 November 2013

Since the public reporting of radiation accidents, there has been an unprecedented effort on the part of national societies, departments, and clinics to improve the quality of care for patients receiving radiation therapy. Benchmarks and quality standards that encourage safe practices have been proposed and are currently being floated through Congress. Yet there remains confusion as well as a lack of adequate response to the problems confronting the complexity and risk associated with modern radiation treatment. The "Target Safely" effort from the American Society for Radiation Oncology is designed to develop broad measures and efforts that enhance safety.[1] However, problems with safety and quality standards like these are that they tend to be too general, lack uniformity in taxonomy or scope, rely upon historic metrics that may have emerged without a sufficient evidence base, focus too narrowly on avoiding complications, and fail to address the role of culture in radiation oncology clinics. That said, the effort to establish broad foundations of a safety environment is valuable; it's just not clear how that will translate to meaningful safety at the level of the patient.

Another contributing factor is that most clinics are removed from the high-level, abstract ideals of safety and guidelines. We live in an environment where clinical intuition and work-arounds are the norm and, quite frankly, expected. Yet perhaps nothing contributes more to poor outcomes and unsafe treatment. Medical intuition implies a trust in our treatment decision against a bet for the patients' future yet we only have hindsight to know whether we were right or wrong. We do not play enough of an active role in building decision making and quality frameworks, and expect safety programs to be built and "managed" by others, such as our administrators and medical societies with an underlying degree of complacency. We like to think of this logic as a moral hazard. Think of it this way, the hazard ratio for describing the association between radiation therapy protocol deviations and overall survival reflects nothing more than treatment planning compliance and quality for patients enrolled on clinical trials (hazard ratio for overall survival, 1.74; 95% confidence interval [CI], 1.28-2.35; $P < .001$).[2] If we can't get it right for patients on clinical trials, can we really trust our intuition for care offered outside of standardized or pathway driven decision making?

How then do we bridge the gap in trust and reality between the broad strokes of a Target Safely program and the needed metrics in the clinic? In their paper entitled "Quality Standards in Radiation Medicine," Donaldson et al[3] have reported on their approach toward classifying multiple quality standards from disparate quality and safety organizations into a more manageable scheme as a potential foundation that translates quality and safety initiatives in the clinic. They propose a 2-category hybrid scheme that classifies each quality standard in the widely benchmarked Donabedian quality framework[4,5] (3 aspects: structure-process-outcome) as well as a new proposed target framework (4 aspects: equipment/clinical process-organization-patient-staff) to which these quality standards are putatively directed. Essentially, the authors have reliably distilled 454 quality standards (451 in the Donabedian category and 409 in the target category) from 8 national or international programmatic quality standards documents into a structured set. The resulting classification provides an efficient framework for the focused review of each existing standard. The 3-tiered Donabedian approach rests on the assumption that having the right structure may yield good processes and that good

See Related Article on page 208.

Conflicts of interest: None.

* Corresponding author. Department of Radiation Medicine, North Shore-LIJ Health System, New Hyde Park, NY 11040.

E-mail address: lpotters@nshs.edu (L. Potters).

http://dx.doi.org/10.1016/j.prro.2013.11.002

processes may culminate in good outcomes. By attempting to cast these standards into the Donabedian framework using kappa-score validated interrater reliability evaluations, the authors have set an important precedent for future directions for quality and safety organizations. Having demonstrated the feasibility of this reliability-assessment guided approach, the work of the authors could be replicated by quality and safety organizations as well as individual radiation medicine departments to assess the adequacy of existing local, national, or international standards, perform gap analyses, and develop better strategies for risk mitigation and quality improvement. The authors should be lauded for these efforts.

Beyond the Donabedian and target categorization of existing quality standards, we believe this work also shows a top-down gap in efforts hitherto to improve quality and safety in radiation medicine from safety or quality organizations. In the Donabedian classification, of the 451 standards reviewed, 63.9% were associated with structure, 25.6% with process and just 9.9% with outcomes. The number of standards aimed toward "structures" was thus 1.8 times that aimed toward "process" and "outcomes" combined. Quality standards were oriented least toward "outcomes" by a significant margin. Once again, this demonstrates the historical approach taken to develop standards in the past directed toward "structures" that highlights a gap in achieving an equitable perspective on quality and safety in radiation medicine. Safety organizations need to consider a more balanced approach to bridge the gaps for future quality standards development.

It is our view that the mere recasting of quality standards into this framework, while an important first step, may not be enough. To build from the appropriate vantage point where the authors have brought us to, a deeper understanding of the linkages between each of the 3 aspects of this framework is an important next step toward the creation of a more informed, comprehensive, and therefore robust set of quality standards.

Reflecting on studies at our own institution over the past few years there are important lessons from the bottom-up that complement the findings of this study. Reviews and analyses of incidents logged in our departmental incident reporting database that incorporate the Donabedian framework have yielded important findings regarding the relationships between the structure, process, and outcome aspects in radiation medicine. Incident learning, both reactive and prospective, have highlighted complexities as well as strong correlations between high-risk procedures in the radiation medicine process and adverse effects on patients, variability in practitioner performance despite the use of departmental quality standards, and the prevalence of error provoking cultural conditions that undermine the effectiveness of the standards in our paperless, accredited, multicenter radiation medicine practice. Based on our work (in press) we feel that quality and safety initiatives development would be most effective if augmented with evidence-based metrics for the mitigation of these associated risks. These metrics serve as quantitative measures of change in quality and safety over time in response to initiatives. We have seen substantial improvements over the past 3 years in our department based on their use and continued guidance for improvements.

Safety and quality remain one of those topics that fail to excite the way protons do. With a low incidence of reportable events our intuition has us believe we are doing "okay" in terms of safety. But as we accumulate data using incident analysis in the Donabedian framework, akin to the work done by the authors, we will likely be surprised with a hazard impact similar to the Ohri et al study.[2] In the meantime, we need to be committed to operational frameworks that may seem counterintuitive, like delaying care instead of rushing care or insisting on pathway-driven treatment protocols for even routine cases.

References

1. Available at https://www.astro.org/Clinical-Practice/Patient-Safety/Target-Safely. Accessed November 1, 2013.
2. Ohri N, Shen X, Dicker AP, Doyle LA, Harrison AS, Showalter TN. Radiotherapy protocol deviations and clinical outcomes: a meta-analysis of cooperative group clinical trials. *J Natl Cancer Inst.* 2013;105:387-393.
3. Donaldson H, Cao J, French J, et al. Quality standards in radiation medicine. *Pract Radiat Oncol.* 2014;4:208-214.
4. Donabedian A. The quality of care. How can it be assessed? *JAMA.* 1988;260:1743-1748.
5. Albert JM, Das P. Quality assessment in oncology. *Int J Radiat Oncol Biol Phys.* 2012;83:773-781.